74

Draft Guidance For Industry

STABILITY TESTING FOR NEW DOSAGE FORMS OF NEW ANIMAL DRUGS

DRAFT GUIDANCE

This document is an annex to the VICH parent stability guidance "Stability Testing of New Animal Drug Substances and Products". It addresses the recommendations on what should be submitted regarding stability of new dosage forms by the owner of the original application, after the original submission for new drug substances and products.

This guidance represents current thinking and does not create or confer any rights for or on any person and does not operate to bind FDA or the public. Alternative approaches may be used if they satisfy applicable requirement.

Comments and suggestions regarding the document should be submitted to Docket No. 97N-[insert number when assigned]. For questions regarding this draft document, contact William G. Marnane, Center for Veterinary Medicine, (HFV- 140), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-594-0678, E-mail: wmarnane@bangate.fda.gov.

U.S. Department of Health and Human Service
Food and Drug Administration
Center for Veterinary Medicine
July 1998

VICH GL4 (STABILITY 2)
February 1998
For consultation at Step 4- Draft 1

STABILITY TESTING FOR NEW DOSAGE FORMS OF NEW ANIMAL DRUGS ANNEX TO THE VICH GUIDANCE ON STABILITY TESTING OF NEW ANIMAL DRUG SUBSTANCES AND PRODUCTS

Recommended for Consultation at Step 4 of the VICH Process on 27 February 1998 by the VICH Steering Committee

THIS GUIDANCE HAS BEEN DEVELOPED BY THE APPROPRIATE VICH EXPERT WORKING GROUP ON THE BASIS OF THE ICH GUIDANCE ON THE SAME SUBJECT AND IS SUBJECT TO CONSULTATION BY THE PARTIES, IN ACCORDANCE WITH THE VICH PROCESS. AT STEP 7 OF THE PROCESS THE FINAL DRAFT WILL BE RECOMMENDED FOR ADOPTION TO THE REGULATORY BODIES OF THE EUROPEAN UNION, JAPAN AND USA.

STABILITY TESTING
FOR NEW DOSAGE FORMS OF ANIMAL DRUGS

Endorsed by the VICH Steering Committee at Step 3 of the VICH Process
27 February 1998

1. GENERAL

The draft VICH Harmonised Tripartite Guidance on Stability Testing of New Animal Drug Substances and Products was issued on February 27, 1998. This document is an annex to the VICH parent stability guidance (VICH GL3) and addresses the recommendations on what should be submitted regarding stability of new dosage forms by the owner of the original application, after the original submission for new drug substances and products. since guidance is not legally binding, an applicant may submit justification for an alternate approach.

2. NEW DOSAGE FORMS

A new dosage form is defined as a drug product which is a different pharmaceutical product type, but contains the same active substance as included in the existing drug product approved by the pertinent regulatory authority.

Such pharmaceutical product types include products of different administration route (e.g., oral to parenteral), new specific functionalist y/delivery systems (e. g., immediate release tablet to modified release tablet) and different dosage forms of the same administration route (e.g., capsule to tablet, solution to suspension).

Stability protocols for new dosage forms should follow the guidance in the parent stability guidance in principle. However, a reduced stability database at submission time may be acceptable in certain justified cases.